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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,593	11/01/2003	Drew R. Ivers	1379-009	1638
32905	7590	09/22/2004	EXAMINER	
JONDLE & ASSOCIATES P.C. 9085 EAST MINERAL CIRCLE SUITE 200 CENTENNIAL, CO 80112			BUI, PHUONG T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,593

Applicant(s)

IVERS, DREW R.

Examiner

Phuong T. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

1. Claims 1-29 are examined in the instant application.

Specification

2. The abstract of the disclosure is objected to because the word "novel" should be deleted, as novelty has not been established; and if the claimed invention is determined to be patentable, then novelty is presumed. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following: the claims recite ATCC Accession information not disclosed in the specification. Applicant is required to provide the corresponding ATCC Accession information in the specification also. Compliance with this requirement may be held in abeyance until patentability is determined.

On page 19, "mosaic" is misspelled.

Drawings

4. No drawing has been submitted in the instant application.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The ATCC Accession No. information in claims 1, 6, 22-23 and 28 is incomplete.

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Claim 20 is an incomplete method claim because it does not result in a plant with modified metabolism. It is suggested that Applicant clarify that the transgene is expressed, thereby producing a soybean plant with modified fatty acid metabolism or modified carbohydrate metabolism.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, 1st paragraph, enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a reproducible process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that Applicant intends to deposit the claimed seed at the ATCC, but there is no indication that the seed has been deposited and there is no indication in the specification as to public availability. If the deposit of the seed is made under the terms of the Budapest Treaty and in compliance with 37 CFR 1.801-1.809, then an

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affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating the seed will be irrevocably, and without restriction or condition, released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the terms of the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become unviable.

The deposit information on page 29 of the specification does not fully comply with the deposit requirements because a proper deposit has not been made; and Applicant failed to state that the deposit will be made under the terms of the Budapest Treaty and in compliance with 37 CFR 1.801-1.809.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

9. Claims 5 and 8-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention lacks written description under current written description guidelines. The claims are drawn to soybean progeny plants having undisclosed identifying characteristics whereby only one parent in the first cross is known. Claim 5 is included because it recites "seed". Deletion of "seed" from claim 5 would obviate this rejection. Applicant should note that no identifying characteristics are set forth for the F1 hybrid progeny. In paragraph [0007] of the specification, Applicant states:

"A most difficult task is the identification of individuals that are genetically superior, because for most traits the true genotypic value is masked by other confounding plant traits or environmental factors."

In paragraph [0008], Applicant further states:

"The breeder has no direct control at the cellular level. Therefore, two breeders will never develop the same line, or even very similar lines, having the same soybean traits."

In paragraph [0009], Applicant further indicates:

"The cultivars which are developed are unpredictable. This unpredictability is because the breeder's selection occurs in unique environments, with no control at the DNA level (using conventional breeding procedures), and with millions of different possible genetic combinations being generated. A breeder of ordinary skill in the art cannot predict the final resulting lines he develops, except possibly in a very gross and general fashion. The same breeder cannot produce the same cultivar twice by using the exact same original parents and the same selection techniques."

If the claimed F1 plant itself cannot be identified by characteristics clearly disclosed in the specification, then it is not even possible to determine whether a plant of unknown parentage is or is not covered by the claim. Thus, F1 progeny plants that are not disclosed by any identifying characteristics are not considered to be possessed by Applicant. There is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained after cross hybridization with an unknown parent, absent further guidance. The breeding techniques disclosed encompasses conventional cross hybridization using two parent plants that are genetically distinct from each other. Each of these breeding techniques would result in a structurally and phenotypically different plant. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Accordingly, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111).

Claim Rejections - 35 USC § 102 and 35 USC § 103

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 5 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eby (US Pat. No. 6162970

(A)). Eby teaches a soybean plant and seed, wherein said plant or seed has imperfect black hilum, purple flower color, brown pod color (same as Applicant's tawny), gray pubescence, indeterminate plant habit, maturity group I and Roundup resistance (col.

6). While the soybean variety of the prior art has a different cultivar designation from Applicant's, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art. At the F1 progeny level, no identifying characteristics are recited to distinguish Applicant's F1 plants from those of the prior art. The claims do not specifically recite a plant whereby "all of the physiological and morphological characteristics" of the SG1330NRR parent are retained. None of the identifying features which distinguish Applicant's plants from those of the prior art are set forth (see written description rejection above). The method

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of producing the plant, namely using soybean SG1330NRR as the only known parent from the cross, would not confer a unique property to the resultant soybean which would distinguish it from the prior art soybean. Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

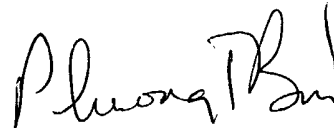
Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Phuong T. Bui', with a stylized flourish at the end.

Phuong T. Bui
Primary Examiner
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9/18/04